

REMARKS

Reconsideration of the present application in view of the following remarks is respectfully requested.

Applicants wish to withdraw the subject application from Appeal and to reopen prosecution thereof. This reply is being filed with a Request for Continued Examination (RCE) in response to the Final Office Action mailed September 5, 2007. Claims 3, 4, and 11-15 are pending and under consideration. Of these, there is a single independent claim 3. Claims 4 and 11-15 depend directly or indirectly from claim 3 and thus include all the elements of claim 3. No amendments are introduced with this response.

***Rejection Under 35 U.S.C. § 102***

Claims 3, 12, 13, 14, and 15 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,379,379 to Wang (hereinafter “Wang”). Applicants respectfully traverse this ground of rejection.

Under 35 U.S.C. § 102, a patent claim is invalid if the claim is anticipated by a prior art reference. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants submit that, under this standard, the Office Action has failed to establish a case for anticipation by Wang of claim 3, and thus claims 12-15 depending therefrom.

Instant independent claim 3, and thus also claims 12-15 depending therefrom, are directed to a stent graft, comprising an endoluminal stent and a graft, and further comprising a vessel wall irritant. Therefore, the claimed subject matter requires at least three elements: a stent, a graft, and a vessel wall irritant. Accordingly, to anticipate the instantly claimed subject matter, Wang must teach or disclose a device having at least all three of these elements. Applicants submit that Wang fails to teach, disclose, or even suggest one required element, namely, the graft. Applicants further submit that the Action has failed to provide adequate rationale for citing Wang as anticipating all three of these required elements. Wang teaches only

a stent having a coating or a sleeve at one or both ends. As taught in Wang, the coating or sleeve is designed to provide a smooth surface at one or both ends of the stent to prevent damage to the vessel wall, and thus to prevent formation and proliferation of scar tissue, which may occur upon insertion of an unmodified stent into a vessel. Wang further teaches that the coating or sleeve may include a bioadhesive to repair the tissue wall in the event of a tear or dissection by the inserted stent.

Applicants strongly disagree with the assertion in the Office Action dated September 5, 2007, that Wang “discloses a stent graft comprising a stent (44) and a graft (46) ....” The Action attempts to further explain this assertion as follows:

Examiner’s position is that with a broadest reasonable interpretation, the sleeve (46) of Wang reference encompasses a graft function and it is considered to be a graft. The sleeve (46) is a tube that has a stent (44) to hold the sleeve open and permit attachment of the sleeve to a body passageway. The sleeve is (46) adapted to prevent the flow of fluids from the inside to the outside of the sleeve. The claimed limitations do not exclude a sleeve (46) placed on the stent (44) from being a graft and the claimed limitations do not limit the claim the stent as claimed to be used for bypassing a damaged body passageway.

Applicants submit that this explanation does not appear to accurately represent the structure or function of a stent graft or the disclosure of Wang. In particular, Applicants submit that the sleeve positioned at one or both ends of a stent, as disclosed in Wang, does not encompass the function of a graft in a stent graft. Applicants further submit that Wang does not describe or even suggest that the sleeve is a tube having a stent to hold it open and to permit its attachment to a body passageway. Applicants thus submit that the sleeve does not correspond to a graft and that Wang does not disclose a graft attached to the stent.

Nevertheless, in view of these assertions, Applicants wish to further clearly distinguish the stent taught in Wang as having a sleeve at one or both ends from the stent graft to which the currently pending claims are directed. Accordingly, Applicants submit in particular that a graft is a tubular structure that serves to transport fluid without flow or leakage of fluid through its walls. A stent is a tubular structure with walls made from an open material, such as a wire mesh. Since fluid can freely flow through the open structure of the walls, a stent cannot serve to transport fluid. A stent

graft is a graft, typically of a form in which some or all of the graft is associated with a stent. Certain forms of stent grafts may have short portions of the ends of the stent extending beyond the ends of the graft. However, there appear to be no stent grafts described in the art wherein the graft portions are associated only with one or both ends of the stent. Accordingly, since graft material forms at least most of the entire length of the structure of a stent graft, no flow or leakage of fluid occurs through the walls of the stent portion of the stent graft, except possibly at the very ends of the stent in those cases wherein the ends of the stent extend beyond the ends of the graft. A stent graft, like a graft, can thus serve to transport fluid and is at least functionally primarily still a graft. A variety of commercially available stent grafts clearly demonstrate such devices are structurally and functionally grafts having stents associated therewith, including, for example, the AneuRx AAAdvantage Stent Graft (<http://www.medtronic.com/physician/aneurx/index.html> (see, Item IX-1 included herewith)); the Talent Thoracic Stent Graft System ([http://medgadget.com/archives/2007/03/talent\\_thoracic.html](http://medgadget.com/archives/2007/03/talent_thoracic.html) (see, Item IX-2 included herewith)); and the FLAIR Endovascular Stent Graft (<http://www.fda.gov/cdrh/mda/docs/P060002.html> (see, Item IX-3 included herewith)).

Applicants submit that, in clear contrast to a stent graft, as described above, the stent taught in Wang, having sleeves at one or both ends, cannot serve to transport fluid, except possibly through short portions at one or both ends, when one or both ends is covered for protection by a sleeve. Fluid will still freely flow through all other portions of the walls that are not covered by a sleeve. Accordingly, Applicants submit that a stent partially covered with a sleeve at one or both ends, even with the broadest reasonable interpretation, is not structurally or functionally equivalent to a stent graft, such as any of those commercially available, as identified above, or as otherwise known in the art. To further clarify, it may be useful to consider one of the common exemplary uses of a stent graft, such as to span and provide an alternative passageway for the flow of blood from one side to the other of a portion of a blood vessel having an aneurysm. In such a use it is the tubular graft that forms the passageway and transports blood, while the stent portion exerts radial pressure to simply hold the tubular graft open

and forces the outer surface of the graft against the inner surface of the vessel wall. The stent taught in Wang, having open mesh walls with a sleeve at one or both ends, would fail in this common use of a stent graft, or for that matter any other use of a stent graft. Accordingly, Applicants submit that Wang clearly fails to teach, disclose, or even suggest, a stent graft.

In summary, Applicants thus respectfully submit that Wang fails to disclose “a stent graft, comprising an endoluminal stent and a graft, wherein said stent graft further comprises a vessel wall irritant...,” as claimed in instant claim 3, and thus in claims 12-15, and in claims 4 and 11 as well, all of which depend directly or indirectly from claim 3. Accordingly, Applicants request that the rejection of claims 3 and 12-15 be withdrawn.

#### ***Rejection under 35 U.S.C. § 103***

Claims 4 and 11 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Wang. Applicants respectfully traverse this ground of rejection and submit that the Action has failed to establish a *prima facie* case of obviousness. In particular, the Action has incorrectly characterized Wang, and it does not serve as the basis for an obviousness rejection of pending claims 4 and 11.

The Action asserts in numbered paragraph 5 at page 4 that Wang “discloses all the limitations of the claims except fails to disclose a stent-graft being bifurcated and the wall irritant being selected from the groups as listed in claim 4.” As discussed in detail above concerning the 35 U.S.C. § 102 rejection, Wang teaches a stent, but fails to teach, disclose, or even suggest, a graft, *i.e.*, one of the required elements in claim 3 (and thus in claims 4 and 11, which depend therefrom). There is no further disclosure in Wang, nor is there any further rationale provided in the Action related to claims 4 and 11, to overcome this deficiency in Wang. Further, regarding claim 11, the Action asserts that “it would have been obvious to modify Wang’s stent having bifurcated configuration....” However, providing a stent with a bifurcated configuration does not overcome the failure of Wang to teach a stent graft. In fact, with a bifurcated stent, it is impossible to envision inserting one or more ends of the stent into sleeve(s), as disclosed in Wang, to form a non-leaking bifurcated alternative fluid passageway. Regarding claim 4, the

Action asserts that the materials to which claim 4 is directed are bioadhesive materials. However, the Action has provided no basis for this mere assertion that the recited vessel wall irritants are in fact bioadhesive materials. Applicants thus submit that, in the rejection under 35 U.S.C. § 103(a), nothing has been provided in the Action or in Wang to overcome the failure of Wang to teach, disclose, or suggest, one of the required elements in pending claim 3 and thus claims 4 and 11 depending therefrom.

In view of the above arguments, Applicants respectfully submit that the Action has failed to establish a *prima facie* case for obviousness of claims 4 and 11 under Section 103. Accordingly, Applicants respectfully request that the obviousness rejection of claims 4 and 11 be withdrawn.

Therefore, in light of the remarks set forth above, Applicants believe that all of the rejections in the Office Action have been overcome. Accordingly, reconsideration and allowance of pending claims 3, 4 and 11-15 are respectfully requested.

If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned at 206-622-4900 to resolve the matter.

The Director is authorized to charge any additional fees due by way of this Reply & Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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Attachments:

Three (3) Web pages